



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1377]

Electronic Study Data Submission; Data Standards; Study Data Standardization Plan

Recommendations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft recommendations for preparing a Study Data Standardization Plan (Standardization Plan). The Standardization Plan is referenced in the Study Data Technical Conformance Guide (Guide).

The Guide supplements the guidance for industry “Providing Regulatory Submissions in Electronic Format--Standardized Study Data” and provides specifications, recommendations, and general considerations on submitting standardized study data using FDA-supported data standards. The Guide recommends that, for clinical and nonclinical studies, sponsors include a plan that describes the submission of standardized study data to FDA. The proposed recommendations describe the information that should be included in the Standardization Plan. The proposed recommendations for creating a Standardization Plan are posted on FDA’s Study Data Standards Resources Web page at

<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>.

DATES: Although you can comment on these recommendations at any time, to ensure that the Agency considers your comments, please submit either electronic or written comments by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the recommendations to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Hillandale Building, 4<sup>th</sup> Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft recommendations for preparing the Standardization Plan.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1192, Silver Spring, MD 20993-002, 301-796-5333, email: [ronald.fitzmartin@fda.hhs.gov](mailto:ronald.fitzmartin@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of draft recommendations for preparing the Standardization Plan. The Standardization Plan is referenced in the Guide. The Guide supplements the guidance for industry “Providing Regulatory Submissions in Electronic Format-

-Standardized Study Data” and provides specifications, recommendations, and general considerations on submitting standardized study data using FDA-supported data standards; it is posted on FDA’s Study Data Standards Resources Web page at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>.

The Guide recommends that, for clinical and nonclinical studies, sponsors include a plan that describes the submission of standardized study data to FDA. The Standardization Plan will assist FDA in identifying potential data standardization issues early in the development program (e.g., pre-investigational new drug application stage). The draft recommendations describe the information that should be included in the Standardization Plan. The recommendations include, but are not limited to, the following: (1) General sponsor information, (2) product information, (3) list of completed studies and standards, and (4) list of planned studies and standards.

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. Electronic Access

Persons with access to the Internet may obtain the proposed recommendations at either <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm> or <http://www.regulations.gov>.

Dated: May 11, 2015.

Leslie Kux,

Associate Commissioner for Policy,

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